

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE BENDAMUSTINE CONSOLIDATED
CASES

)
)
) Civil Action No. 13-2046-GMS
) **CONSOLIDATED**
)
)

MEMORANDUM

I. INTRODUCTION

The plaintiff Cephalon, Inc. (“Cephalon”), pursuant to the Hatch-Waxman Act, filed patent infringement actions against Sagent Pharmaceuticals, Inc.; Dr. Reddy’s Laboratories, Ltd., and Dr. Reddy’s Laboratories, Inc.; Uman Pharma, Inc.; and InnoPharma, Inc. (collectively, “the Moving Defendants”), alleging, among other things, that the Moving Defendants have infringed at least one or more claims of U.S. Patent Nos. 8,436,190 and/or 8,609,863 (“the ’190 and ’863 patents”) by the filing of their respective Abbreviated New Drug Applications (“ANDA”) with the FDA. Presently before the court is the Moving Defendants’ Motion for Judgment on the Pleadings with respect to Cephalon’s claims for infringement of the ’190 and ’863 patents. (D.I. 58.) For the reasons that follow, the court will grant the Moving Defendants’ motion.

II. BACKGROUND

The Moving Defendants (among others) triggered these lawsuits under the Hatch-Waxman Act by filing their respective ANDAs, seeking FDA approval to market a generic version of Cephalon’s TREANDA® product. The ’190 and ’863 patents are among a number of patents listed for TREANDA® in the FDA’s Orange Book. The ’190 and ’863 patents claim compositions/preparations that include tertiary-butyl alcohol (“TBA”). The Moving Defendants’ ANDA products do not contain TBA. (D.I. 59.)

III. STANDARD OF REVIEW

When deciding a Rule 12(c) motion for judgment on the pleadings based on an allegation that the plaintiff has failed to state a claim, the motion “is analyzed under the same standards that apply to a Rule 12(b)(6) motion.” *Revell v. Port Auth.*, 598 F.3d 128, 134 (3d Cir. 2010). That is, the court must view all facts and inferences drawn from the pleadings in the light most favorable to the non-moving party. *Green v. Fund Asset Mgmt., L.P.*, 245 F.3d 213, 220 (3d Cir. 2001). But the court is “not compelled to accept unsupported conclusions and unwarranted inferences, or a legal conclusion couched as a factual allegation.” *Baraka v. McGreevey*, 481 F.3d 187 (3d Cir. 2007) (internal citations and quotation marks omitted). The issue for the court is “not whether the plaintiff will ultimately prevail, but whether the claimant is entitled to offer evidence to support the claims.” *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974).

IV. DISCUSSION

The instant motion raises a narrow question for the court’s consideration. The parties appear to agree that Cephalon’s theory of infringement for ’190 and ’863 patents is premised on the doctrine of equivalents, rather than literal infringement. (D.I. 108 at 1, 7–8.) Moreover, the Moving Defendants concede that Cephalon has satisfied the basic pleading requirements to provide adequate notice. (D.I. 184 at 2–3.) Therefore, the only issue is whether Cephalon’s doctrine-of-equivalents arguments are barred by the “disclosure-dedication rule.”

As an initial matter, Cephalon attacks the Moving Defendants’ process in filing this motion. If “matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56.” Fed. R. Civ. P. 12(d); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (“[A] district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings.”). Cephalon argues

that the Moving Defendants reliance on the content of their respective ANDA filings converts this Rule 12(c) motion into a premature motion for summary judgment. The court may, however, accept additional documents “without converting the motion [to dismiss] into one for summary judgment” if they are “*integral to or explicitly relied upon in the complaint.*” *In re Burlington Coat Factory*, 114 F.3d at 1426 (alteration in original). “[W]hat is critical is whether the claims in the complaint are ‘based’ on an extrinsic document and not merely whether the extrinsic document was explicitly cited.” *Id.* The court is satisfied that the ’190 and ’863 patents, their file histories, as well as the Moving Defendants’ ANDA filings are all properly before the court, even at this preliminary stage. *See AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1378 n.5 (Fed. Cir. 2012). Cephalon does not raise a challenge to the documents’ authenticity. Indeed, the patents and the ANDA filings comprise the entire basis for Cephalon’s complaints against the Moving Defendants—Cephalon’s argument that they are not “integral” is puzzling.

Finding no procedural flaw in the Moving Defendants’ motion, the court turns to the merits of the disclosure-dedication rule:

[W]hen a patent drafter discloses but declines to claim subject matter, . . . this action dedicates that unclaimed subject matter to the public. Application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would conflict with the primacy of the claims in defining the scope of the patentee’s exclusive right.

See Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co., 285 F.3d 1046, 1054 (Fed. Cir. 2002) (internal quotation marks omitted). But the rule “is not without restriction” and “does not mean that any generic reference in a written specification necessarily dedicates all members of that particular genus to the public. Rather, the disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed.” *SanDisk Corp. v. Kingston Tech. Co.*, 695 F.3d 1348, 1363 (Fed. Cir. 2012) (internal quotation marks

omitted) (quoting *PSC Computer Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004)). “Whether the disclosure-dedication rule prevents a patentee from pursuing a doctrine of equivalents infringement theory is a question of law” *Id.* at 1364.

The common specification for the '190 and '863 patents includes a list of possible organic solvents:

[T]he organic solvent is selected from one or more of tertiary butanol, n-propanol, n-butanol, isopropanol, ethanol, methanol, acetone, ethyl acetate, dimethyl carbonate, acetonitrile, dichloromethane, methyl ethyl ketone, methyl isobutyl ketone, 1-pentanol, methyl acetate, carbon tetrachloride, dimethyl sulfoxide, hexafluoroacetone, chlorobutanol, dimethyl sulfone, acetic acid, and cyclohexane.

'190 Patent, col. 5, ll. 6–14; *see also id.*, col. 16, ll. 39–50.¹ The specification identifies TBA as the “more preferred organic solvent” of the list. '190 Patent, col. 5, l. 16; *see also id.* col. 16, ll. 41–49 (“The most typical example of the solvent used to prepare this formulation is tertiary butanol (TBA). Other organic solvents can be used including [list].”) But the '190 and '863 patents only claim compositions or preparations containing TBA—the other enumerated solvents are not specifically claimed.

This is not a situation where the specification makes a “generic reference” to a broad genus, such as all “organic solvents.” *See SanDisk*, 695 F.3d at 1363. Rather, as illustrated in the above quote, the specification identifies *precise alternatives* to TBA. Thus, it is unnecessary to inquire into whether “one of ordinary skill in the art could identify the subject matter that had been disclosed [but] not claimed”—the list is self-explanatory. As a result, the court is confident that this issue is capable of being resolved at the motion to dismiss stage.

¹ For convenience, the court only cites the '190 patent for references to the common specification.

The question therefore becomes whether the Moving Defendants' ANDA products contain one or more solvents that are disclosed but not claimed in the '190 and '863 patents. The ANDA filings confirm that they do. (D.I. 59.)² As such, the court agrees with the Moving Defendants that the disclosure-dedication rule bars Cephalon from arguing infringement of the '190 and '863 patents on a doctrine-of-equivalents theory. "[A] patentee cannot narrowly claim an invention to avoid prosecution scrutiny by the PTO, and then, after patent issuance, use the doctrine of equivalents to establish infringement because the specification discloses equivalents." *Johnson & Johnston*, 285 F.3d at 1054. By claiming only TBA from among the listed organic solvents, the patentee effectively disclaimed the remaining solvents in the list and cannot employ the doctrine of equivalents to bring them back within the scope of the '190 and '863 patents.

Cephalon argues that the disclosure-dedication rule does not apply here because Cephalon did not "decline to claim" or "deliberately [leave] unclaimed" the additional solvents. Cephalon tried to claim the additional solvents previously during the prosecution of the '190 patent. (D.I. 108, Ex. A.). And Cephalon in fact succeeded in claiming them in a continuation application that issued as U.S. Patent No. 8,461,350 ("the '350 patent"). But Cephalon's arguments inject unnecessary layers of complexity into what is a relatively straightforward doctrine. Federal Circuit law is well settled that intent is not relevant to the disclosure-dedication rule. *See Johnson & Johnston*, 285 F.3d at 1053 n.1 ("The patentee's subjective intent is irrelevant to determining whether unclaimed subject matter has been disclosed and therefore dedicated to the public."); *see also Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1333 (Fed. Cir. 2004) ("[I]ntent is not part of the *Johnson & Johnston* disclosure-dedication analysis."). The district court cases cited by

² Cephalon does not dispute that the solvents recited in the specification cover those present in the Moving Defendants' ANDA products. (D.I. 108 at 9–10 ("[O]riginal claims 20 and 21 of the application that issued as the '190 patent recited the solvents [which mirror the list found in the specification] used by Defendants in their ANDA Products.").)

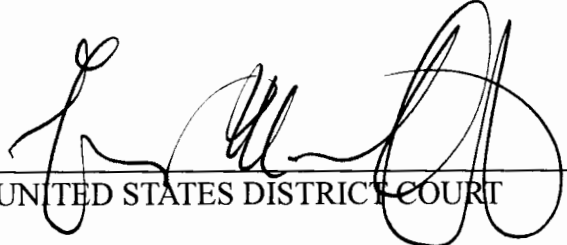
Cephalon plainly misconstrue the holding of *Johnson & Johnston*, the leading Federal Circuit case on the rule. See *Janssen Prods., L.P. v. Lupin Ltd.*, No. 10-5954 (WHW), 2014 U.S. Dist. LEXIS 155248 (D.N.J. Mar. 12, 2014); *Rosby Corp. v. Stoughton Trailers, Inc.*, No. 95 C 0511, 2003 WL 22232802 (N.D. Ill. Sept. 26, 2003). The fact that claims covering the disclosed subject matter were ultimately allowed in another patent has no bearing on whether they were disclaimed in the patent in question. The holding in *Johnson & Johnston* made this explicit: “A patentee who inadvertently fails to claim disclosed subject matter . . . is not left without remedy. . . . [A] patentee can file a separate [continuation] application claiming the disclosed subject matter.” *Johnson & Johnston*, 285 F.3d at 1055. Like the plaintiff in *Johnson & Johnston*, Cephalon did just this with the ’350 patent. See *id.* (“Johnston took advantage of [this] option[] by filing two continuation applications that *literally* claim the relevant subject matter.” (emphasis added)).

In the ’190 and ’863 patents, Cephalon disclosed but did not claim the additional organic solvents. Therefore, *as it relates to these patents*, the subject matter was disclaimed and dedicated to the public. See *Mahn v. Harwood*, 112 U.S. 354, 361 (1884) (“[W]hat is not claimed is public property.”). Of course, this does not rule out the possibility that another patent may still preclude public use, such as the ’350 patent. But Cephalon’s allegations that the Moving Defendants infringe the ’190 and ’863 patents under the doctrine of equivalents are barred as a matter of law by the disclosure-dedication rule.

V. CONCLUSION

For the foregoing reasons the court will grant the Moving Defendants’ Motion for Judgment on the Pleadings with respect to Cephalon’s claims for infringement of the ’190 and ’863 patents. (D.I. 58.)

Dated: April 29, 2015



UNITED STATES DISTRICT COURT